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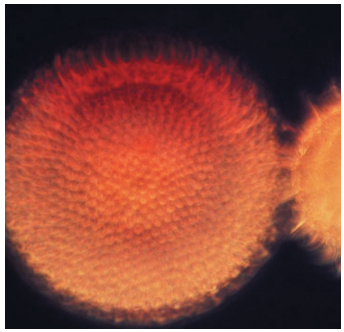
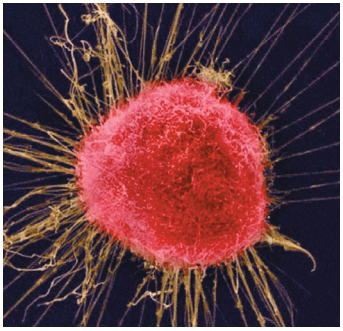
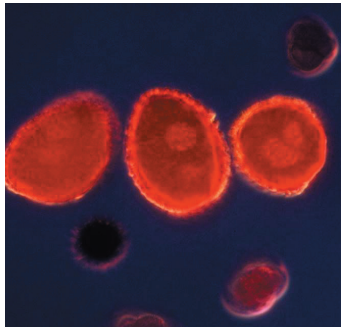


STEM CELL





RESEARCH

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STEM CELL RESEARCH

I. ACRONYMS

AScell: Adult stem cell.

ASCR: Adult stem cell research.

Blastocyst: An embryo between 5-7 days of development.

Cloning: Process of replicating an organism.

Differentiated: A specialized, mature cell type, i.e., skin cell, liver cell.

Embryo: A human embryo is the earliest stage of a human organism, from the single cell up to 8 weeks of development.

EScell: Embryonic stem cell.

ESCR: Embryonic stem cell research.

IVF: In Vitro Fertilization.

Non-somatic cells: Germ cells (sex cells) such as sperm and egg cells.

Plasticity: The ability of stem cells to "differentiate" from one tissue into other tissues.

Pluripotent: The ability of stem cells to turn into multiple cell types.

Reproductive Cloning: Implanting cloned embryos to produce a baby.

SCNT: Somatic Cell Nuclear Transfer, i.e., human cloning.

Somatic Cells: Body cells, such as skin cells, with a total of 46 chromosomes.

Stem Cell: These are non-specialized cells that can "differentiate" into more mature cells.

Therapeutic Cloning: Creating and destroying cloned embryos for research.

Undifferentiated: Unspecified cells that can turn into any other cell type.

II. THE SCIENCE OF STEM CELLS

Summary:

- **EScells** are declared "most promising" by ESCR advocates because they easily differentiate into all cell types. This same quality, however, makes them very uncontrollable and prone to undesirable outcomes like tumors.
- **ESCR** has major hurdles to overcome: inherent biological instability, few animals models on which to build, and immune rejection problems. As a result human treatments are decades away if at all.
- **ASCR** is well ahead of ESCR. There are many animal models on which to build, human treatments now being researched and immune rejection is not an issue.

Background:

POTENTIAL:

Proponents claim that EScells are the "most promising" to cure 100 million patients.

Because EScells are "pluripotent," proponents claim they are the most promising to treat numerous degenerative diseases. Because EScells become every tissue type during normal embryonic development, proponents believe that they might be able to extract the stem cells and turn them into desired tissues in a Petri dish.

Proponents have argued that because EScells can grow "indefinitely," they will be useful for treating various diseases. Researchers can take a few EScells and replicate them in the lab to create an EScell line that can reproduce repeatedly.

Although there have been very modest results in only a handful of animal models, proponents claim that EScells have the greatest potential to treat humans diseases.

PROBLEMS:

EScells face major scientific hurdles.

Despite what ESCR advocates would have us believe, research on EScells shows that they have inherent biological problems that make treatment for human disease unlikely in the next decade or beyond. Indeed, James Thomson, who discovered human EScells in 1998, claims that EScells are susceptible to forming cancerous tumors. The transformation of EScells into adult tissue is difficult to control. To quote Doug Melton of Harvard, who derived 17 new EScell lines with private funds, "Normally, if you take an EScell, it will make all kinds of things, sort of willy-nilly."

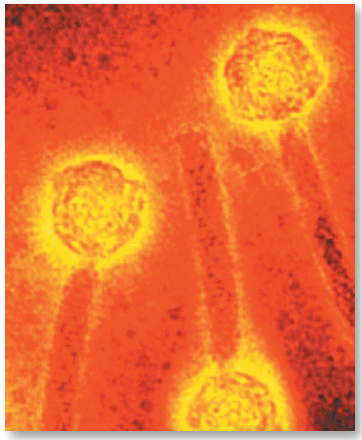
EScells can also be subject to immune rejection. This is because embryos and the stem cells derived from them will have a different genetic make-up from the genetic make-up of a potential patient. At best, patients will have to use severe immuno-suppressive drugs to prevent immune rejection. EScells are not close to being used in human clinical trials.

There are **NO** current treatments of humans with EScells.

ADULT STEM CELLS (AScells):

While celebrities and politicians have been attacking the President's ESCR policy, scientists have been quietly making rapid progress in the treatment of a variety of

diseases with AScells. Under the President's current policy, ASCR in animals and humans have received over $360 million in federal funds over the past two years. Human clinical trials for these promising therapies face serious obstacles, in part due to the politicization of this scientific debate, despite the significant medical advances made in the treatment of Parkinson's disease, diabetes, and spinal cord injury using AScells.



- AScells are found throughout body, and provide a diverse source of stem cells that will have the same genetic make-up as the patient.

- AScells have been used in animals models to treat a variety of diseases, such as diabetes, spinal cord injury, blood diseases, and Parkinson's.

Though treatments with AScells still require more research, AScells have already been used successfully in over 45 clinical trials to treat humans. Just last year, it was reported that researchers in California have reversed the symptoms of Parkinson's disease in a man with his own neural stem cells; clinical trials using this approach are being extended to additional patients. Furthermore, AScells are being used in human clinical trials to restore heart function after severe heart attacks.

ADULT STEM CELL THERAPIES	EMBRYONIC STEM CELL THERAPIES
Human Therapies	**Human Therapies**
Parkinson's	0
Cartilage Defects	0
Blindness	0
Systemic Lupus	0
Multiple Sclerosis	0
Rheumatoid Arthritis	0
Severe combined immunodeficiency disease	0
Cancers such as leukemias, solid tumors, neuroblastoma, non-Hodgkin's lymphoma, and renal cell carcinoma	0
Sickle Cell Anemia	0
Spinal cord injury, modest improvement	0
Liver Disease	0
Animal Therapies	**Animal Therapies**
Brain Damage Diabetes Parkinson's Cancer Cerebral Palsey Retinal Damage Heart Damage Liver Disease Multiple Sclerosis Sickle Cell Anemia Spinal Cord Injury Lou Gehrig's Disease	Parkinson's in rats: 50% of rats had modest improvement, but 20% died of brain tumors. Spinal Cord Injury: Slight functional recovery in animals, similar results not replicated in human studies.

III. POLICY HISTORY OF STEM CELLS

Summary:

- **1975-1996:** Human embryos in the womb are protected as "human subjects" in federally funded research.
- **1996-2000:** Dickey-Wicker appropriations rider has prevented federal funding for any research in which embryos are destroyed.
- **2000:** The Clinton Administration approved NIH guidelines that would have allowed federal funding for research on stem cells derived from human embryos, so long as the specific act of destroying the embryos was not performed with federal funds.
- **2001:** On August 9, 2001, President Bush announced that he was going to begin federal funding of research on stem cell lines derived from human embryos that had been killed prior to his announcement.

Background:

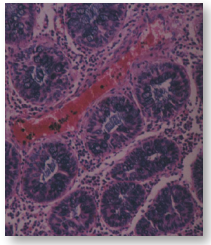
- In 1975, the federal government recognized that human embryos in the womb are to be protected as "human subjects" in federally funded research. It is important to note that in the current debate, the human embryos that researchers want to destroy for their stem cells are at the same stage of development as those embryos in the womb that are protected by federal regulations.
- Since 1996, the Dickey-Wicker appropriations rider has prevented federal funding for any research "in which" embryos are destroyed (P.L. 104-99). The law states that federal funds may not be used for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" (in the womb) according to federal regulations. Since 1996, federal law has prohibited the use of federal funds to pay for research that would result in the killing of human embryos, placing them at risk, including research in which federal dollars do not directly pay for the direct destruction of the human embryo.
- In 2000, NIH guidelines approved by the Clinton Administration allowed federal funding for research on stem cells derived from human embryos, so long as the specific act of destroying the embryos was not performed with federal funds. These new rules, promulgated by then NIH Director, Harold Varmus, were based on a 1999 HHS General Counsel memo (Raab memo) expressing the opinion that the use of federal tax dollars for research using such stem cells would not violate the Dickey-Wicker ban as long as federal funds did not pay for the act of killing the embryo. Though these rules were issued in 2000, President Bush prevented them from being implemented.
- President Bush's August 9, 2001 policy: On August 9, 2001, President Bush announced, in an address to the nation, that he was going to begin federal funding of research on stem cell lines derived from human embryos that had been killed prior to his announcement. Those who want to fund research on additional EScell lines claim that Bush's policy "bans stem cell research," or "is too restrictive." The fact is that Bush's policy for the first time allowed federal funding of ESCR. Some conservatives strongly disapproved of this policy, whereas others thought the policy was ethically defensible as a political compromise that prevented implementing the NIH

guidelines from 2000. Both the Bush and Clinton Administrations seem to have accepted the premise from the Raab memo, that Dickey-Wicker would not be violated so long as funds aren't used on research that kills the human embryo. Bush's policy differs substantially from the Clinton rules in that, though the Clinton rules would have prevented using funds to directly destroy human embryos, they would have created a continuing financial incentive to create and destroy human embryos for research purposes. In contrast, Bush's policy not only ensures that no funds will be used to directly destroy embryos, since it restricts funds to stem cells that were derived from embryos in which the life-and-death decision had been previously made, it also avoids any financial incentive to create more embryos for destructive research.

- Current Status: Since August 9, 2001, the NIH set up a human EScell registry that lists lines that are eligible to receive federal funding and is funding infrastructure grants to make the EScells available. NIH had determined that there are 78 EScell lines that are eligible for federal funding in accordance with the President's policy. Since that time, NIH has worked to attract researchers to apply for grants to perform research on the eligible lines. Of the 78 eligible lines, 22 are currently available for federally funded research. The NIH states that these EScell lines reproduce indefinitely, and the NIH says that they have been able to fulfill requests for basic research. Even though there have not been any breakthroughs in the federally funded basic research on human embryos, and there continue to be breakthroughs with ethical ASCR, some groups and Members of Congress are mounting an effort to allow unlimited numbers of human embryos to be killed in federally funded research.

IV. ETHICS OF EMBRYO STEM CELL RESEARCH

Summary:



- Debate centers around this theme: Sanctity of Life vs Quality of Life.
- Can/should one life be forfeited to improve another?
- Federal funding of additional ESCR will provide a financial incentive to create more embryos solely for research.
- Should ESCR be federally funded when there are ethical alternatives such as ASCR?
- Shouldn't medical research be informed and constrained by the ethical norms of the community?

Background:

Proponents of federal funding of ESCR argue that EScells are the most promising to treat upwards of 100 million patients. Although they claim that it is unethical to create human embryos for the sole purpose of destructive research, they argue it is ethical to fund research on "leftover" human embryos that "would otherwise be discarded." They are referring here to embryos created by in vitro fertilization (IVF) that have not been implanted to produce children.

Despite the claims of some proponents that we should only use leftover embryos, expanding Bush's policy to spend federal funds on more EScell lines will create an unethical incentive to create additional human embryos that will be destroyed for their stem cells. The problem is that proponents of additional funding will not stop at calling for research on "excess" embryos. In fact, many of them are already advocating for the creation of embryos for research through cloning.

1

Federal funding of additional ESCR will provide an incentive to create more embryos solely for research. Even if researchers cannot use federal funds to directly destroy the embryos, federal funding of research on new EScell lines will create a market where some scientists create and kill the embryos for their stem cells and turn around and sell them to other researchers who receive the federal funds.

2

Some "pro-life" members of Congress support funding of ESCR on the basis that this research could save the lives of people with debilitating diseases. The claim is that it is ethically permissible to destroy some lives in the hope that one day other lives may be saved. This obfuscation of the term "pro-life" is based on a utilitarian ethic. It is unethical to destroy some human lives for the betterment of the lives of others. Just as it is unethical to use human fetuses for their organs, it is unethical to kill human embryos for their stem cells. Such reasoning seriously undermines human dignity of all humans regardless of age.

The fact that some embryos may eventually die does not make it ethically right to kill them. Just because a person who has a severe stroke may die does not mean it is ethically right to kill that patient for potentially beneficial medical research or organ harvesting.

3

ESCR should not be funded when there are ethical alternatives such as AScells. In 1999, even President Clinton's National Bioethics Advisory Commission (NBAC) acknowledged broad agreement in our society that early human embryos "deserve respect as a form of human life" (NBAC, Ethical Issues in Human Stem Cell Research, 1999, p. ii). The Commission actually concluded that research requiring the destruction of these human lives should be seen as a last resort, saying: "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research" (Id., p. 53). The Commission recommended funding ESCR research because it thought at that

time that no alternatives existed; but it said this factual judgment "must be revisited continually as science advances" (Id.). Since that time, over 70 human diseases have been successfully treated with AScells, demonstrating that ethical alternatives to EScells do exist.

CONCLUSION

At the heart of this debate is not whether "ideology" stands in the way of medical research, but whether medical research should be informed by any ethical norms at all. The debate is over whether science will continue to serve humanity or whether humanity will be become guinea pigs for science.

As a society we demand that human life is preserved as much by the process of medical research as by the treatments that research seeks to produce. Using one class of citizens for the medical benefit of another is nothing more than slavery. Such attempts made in the name of science, such as the Tuskegee syphilis trial conducted on African-Americans in Alabama as recently as 1972, have been strongly condemned by politicians from both parties.

AS A SOCIETY WE DEMAND THAT HUMAN LIFE IS PRESERVED AS MUCH BY THE PROCESS OF MEDICAL RESEARCH AS BY THE TREATMENTS THAT RESEARCH SEEKS TO PRODUCE.

Far from being divisive, the President's policy accommodates the pluralism of views held by our country. While permitting ESCR on pre-existing EScell lines, and permitting the creation of new EScell lines in the private sector, the President has prevented taxpayers from being forced to pay for research which many consider unethical. Yet, while these so-called "restrictions" have been in place, ethical ASCR has produced a plethora of medical advances and treatments. AScell therapies are moving into clinical trials, which have real potential to bring effective treatment and cures to patients suffering from diabetes, Parkinson's, heart failure, and spinal cord injury in the near future.

V. MEDICAL BREAKTHROUGHS AND THE ROLE OF THE FEDERAL GOVERNMENT

Medical Breakthroughs Do NOT Depend on the Federal Government

Summary:

- Many of our nation's medical breakthroughs and discoveries took place without any federal funding.

Background:

Because the NIH is the largest biomedical research institution in the world, many Americans believe that all medical progress requires NIH funding. **Wrong.**

American ingenuity has never been dependent on government support.

In fact, throughout our nation's history, several significant medical breakthroughs were made in the absence of federal funding.

Here is a short list of some of those successes:

- In 1991, scientists at Pfizer discovered a class of compounds, including a drug called Sildenafil, useful for treating heart problems such as angina. By 1994, researchers at Pfizer observed during the course of clinical trials that Sildenafil also allowed men to reverse erectile dysfunction. In 1998, Sildenafil, or Viagra as it is commonly known, became the first FDA approved pharmaceutical compound for treating impotence.

- In the 1940's O. T. Avery, while working at the privately funded Rockefeller Institute, discovered that DNA was "the molecule of inheritance," the means by which genetic information was passed from generation to generation.

- In 1987, Eli Lilly introduced Prozac, an antidepressant that has helped millions of Americans combat depression. Eli Lilly researcher Ray Fuller developed Prozac in the search for a compound that would control depression by altering serotonin levels. In 2002, 40 million patients in over 90 countries were using Prozac.

- In the 1950's, Stuart Adams, a scientist working at the Boots Company in Britain screened over 600 new organic acids looking for anti-inflammatory drugs that would control pain, particularly among sufferers of rheumatoid arthritis. The safety and efficacy of ibuprofen has resulted in its being sold over the counter to millions world wide under the brand names Advil, Motrin, and Nuprin.

(Sources: "The Free Market of Scientific Research," by Aaron Steelman in The Freeman, May 1998, Vol. 48, No. 5)

VI. WHERE IS THE INTERNATIONAL COMMUNITY ON STEM CELL RESEARCH?

Summary:

- Some 27 nations have specifically banned therapeutic cloning.
- Only 6 nations specifically promote cloning for stem cell research in their governmental policy.
- Germany supports a complete ban on embryo research and cloning.

Background:

WHERE DOES U.S. POLICY STAND IN LIGHT OF INTERNATIONAL LAWS REGARDING ESCR AND CLONING?

Countries with Bioethics Policies similar to or more restrictive than the Bush Policy:

- Austria
- Australia
- Canada
- Costa Rica
- Denmark
- Estonia
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Israel
- Latvia
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Russia
- Slovenia
- Slovak Republic
- Spain
- Switzerland

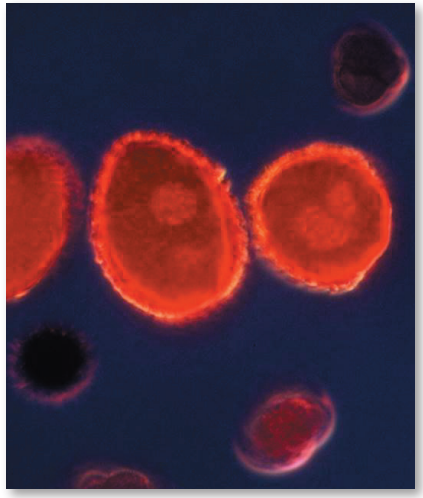
Countries with Bioethics Policies more permissive than the Bush policy:

- Belgium
- China
- Finland
- India
- Japan
- Singapore
- South Korea
- South Africa
- Sweden
- United Kingdom

- Germany, home to the one of the largest biotech industries in Europe, and currently governed by some of the strongest left wing elected officials in Europe, has banned destroying human embryos for stem cell research. They have also banned the importation of all EScell lines created after January 2002. This policy is more restrictive than U.S. policy. Germany has remembered its past to guide its future.

- In addition, Austria, Norway, Italy, Portugal, and Ireland forbid any research on the human embryo, including ESCR and cloning.

- France, Canada, Australia, Norway, Italy, Germany, Austria, Denmark, Switzerland, Greece, Ireland, and Portugal have each banned all forms of human cloning, including so-called "therapeutic cloning." In the process of therapeutic cloning, the cloned embryo is destroyed and its stem cells extracted for further research.



In considering the moral and ethical implications of human cloning and ESCR, President Bush has strong international allies, **including France and Germany!**

VII. WILL ESCR LEAD TO HUMAN CLONING?

Summary:

- Proponents of ESCR want to pave the way for human cloning, which is their ultimate goal.

Background:

A recent New England Journal of Medicine editorial makes it clear that the ultimate goal of researchers is the free and unfettered access to federal dollars to create and destroy human embryos for research purposes, and to employ human cloning as the method of choice:

> *"An even more restrictive (than the current Bush policy) element of government policy prohibits the use of funds for 'the creation of a human embryo or embryos for research purposes..." "...The Dickey Amendment prohibits federally funded scientists from deriving lines that model human disease. The use of somatic-cell nuclear transfer (human cloning) to generate pluripotent lines from patients... hold promise for combining gene therapy."*
>
> ***--George Daley M.D. PhD. NEJM, August 12, 2004***

In other words, Dr. Daley is saying that President Bush's ESCR policy is not the real problem. Instead, Daley is arguing that because of a policy Congress and President Clinton signed into law nearly 10 years ago and have approved every year since, scientists are unable to use taxpayer dollars to create and destroy human embryos. The real "obstacle" for Daley is not President Bush's policy; it's the policy of Congress that prevents taxpayers from paying for unethical research, including the development of human cloning.

That admission is as plain as it gets, and he has company.

Other proponents have also let it slip as to what they really want to see in this brave, new world they would like to create.

House floor debates in 2001 and 2003 on human cloning demonstrate that proponents of ESCR really believe that we need human cloning.

Representatives argued that stem cells from normal IVF embryos are problematic because they do not have the genetic make-up of the patient. As such, the stem cells will cause an immune rejection. To get around this problem, proponents argue that we need embryos that are cloned from the patient, so that the genetic make-up is identical, and the stem cells won't cause an immune rejection.

Some examples from the 107th & 108th human cloning debates in the Congressional Record:

> *"This type of research [cloning] is truly the clinical extension of stem cell research because without this research we will never have islet cells for diabetics"*

> *"The best way to be able to actually maybe get a therapeutic use out of this research [ESCR], actually cure cancer, cure Parkinson's, cure Alzheimer's, cure juvenile diabetes, the actual way to do that is to develop [cloning] research to develop a therapy to actually put the stem cells into the body, and that is exactly what is being done here"*

> *"... potential immunological rejection of human ES-derived cells might be avoided for by using nuclear transfer technology [human cloning] to generate these cells."*

VIII. FREQUENTLY ASKED QUESTIONS ABOUT STEM CELLS

Are all "leftover" IVF embryos discarded as some claim?

NO Proponents of federal funding for more ESCR argue that human EScells hold the most promise for the treatment of 100 million patients. Although they claim that it is unethical to create human embryos for the sole purpose of destructive research, they argue it is ethical to fund research on "leftover" human embryos that "would otherwise be discarded." They are referring here to embryos created by in vitro fertilization (IVF) that have not been implanted to produce children.

Proponents argue that we should fund research on unused IVF embryos, estimates of which ranged from 100,000 to 200,000. In 2003, a Rand report claimed that there are an estimated 400,000 frozen embryos in storage in the United States. This report generated a renewed call for President Bush to expand his policy to fund research on these new embryos, especially since, according to ESCR proponents, "they will be destroyed anyway."

However, according to the Rand report, **87% of the 400,000 frozen embryos are destined for later implantation by the parents**. Currently, only 3% of "unused" IVF embryos are designated for research, which means that about 11,000 frozen embryos are potentially available for ESCR.

Will proponents of federal funding for ESCR be satisfied with only using "leftover" IVF embryos?

NO Even if ALL of the above "available" embryos were made available for research, the best scientific estimate on the number of potential EScell lines derived from these embryos would be much more limited. The Rand report claims that of the 11,000 embryos designated for research, only 65% of frozen embryos may survive the thawing process. Of these, 25% may survive to the blastocyst stage, that is, about 5-7 days when EScells are extracted. Of these, 15% may yield a viable EScell line. The approximate number of EScell lines that could be derived from existing embryos is 275 cell lines at most.

Bottom-line: proponents for ESCR will have to create more embryos for the sole purpose of research.

Is it true that "leftover" IVF human embryos will never become fully human?

NO Some proponents of ESCR claim that we should fund this research because "leftover" embryos cannot even become human beings. They argue that we should use them for research rather than allow the human embryos to go to waste.

This argument begs the question. The only way that "leftover" embryos will not become fully human is if scientists kill them to extract their stem cells, or if they die of natural causes. The truth is that many frozen embryos can be used for later reproduction by their parents. Frozen embryos can be also be adopted by other parents wanting to have their own children.
[See: http://www.snowflakes.org/]

Is there more than one type of "stem cell research?"

YES Stem cells are found in many tissues of the human body, and these are called "AScells." AScells are found in bone marrow, spleen, liver, nasal tissue, fat, brain, and umbilical cord blood. Stem cells are also found in the embryo and can be derived by killing the embryo between 5-7 days of development.

Is there a ban on ESCR?

NO ESCR is legal and unrestricted at the federal level, so researchers can create and kill as many embryos as they choose. The current debate concerns whether taxpayers should pay for research in which embryos are killed for their stem cells. This debate is not about "stem cell research." It is legal to perform research with stem cells that exist throughout the body, such as pancreas, liver, bone marrow, nose, brain, and it is legal to do research on human EScells. Nor is this debate about whether we should ban human cloning, a process in which cloned

human embryos are produced for research or reproduction. The question is whether the federal government should fund destructive human embryo research, the same as the question of whether we should use federal funds to pay for abortions. Both issues concern the use of taxpayer funds to destroy human lives. This is not a debate over the legality of the issue, but whether the federal government funds and, therefore, promotes destructive embryo research.

Does President Bush's administration fund ESCR?

YES On August 9, 2001, President Bush announced a policy to allow federal funding on EScells that were derived from human embryos that had been previously destroyed. This was the first time federal funds were allowed for human ESCR. Specifically, human EScells created before August 9, 2001 are eligible for federal funding. Currently, 78 EScell lines are eligible for funding, and 22 of those currently receive federal funds. This decision did not ban or restrict ESCR in the private sector.

Is President Bush funding less than he promised?

NO Neither the Bush Administration or Congress has limited the amount of federal funding that can be applied to the research on the 78 EScell lines approved by President Bush's ESCR policy. In 2003 alone, almost $25 million was spent on ESCR, with more funds available as qualified researchers apply. There are now 22 human EScell lines currently being studied with federal funds.

As the Director of the NIH, Elias Zerhouni, noted: "by putting this policy into place, the President opened up **an unlimited source of Federal funds for meritorious research using eligible hESCs [human EScell lines]."**

To put it simply, NIH has a $28 billion budget and has ample resources for research on the 78 approved human EScell lines through federal grants.

"The President remains committed to this policy, and it is working. Under his Administration, federal funding for ESCR has grown from zero in 2001 to $24.8 million now, ***with no cap on future funding***."

--Elias Zerhouni, M.D., June 2003, emphasis added.

Furthermore, the NIH is funding programs to train scientists in human ESCR so that more researchers will be able to qualify for federal ESCR funding. The NIH is funding five courses that provide scientists opportunities to gain hands-on experience with human ESCR in addition to a range of grants that support stem cell research career pathways and multi-disciplinary exploratory stem cell research centers.

Under the President's policy, research on the approved human EScell lines is moving full-steam ahead, with ample funding and infrastructure support.

Does the derivation of new lines of human EScells for research purposes mean the purposeful creation and then destruction of human embryos?

YES Given the limited number of human embryos that are truly "available" from current stores of frozen IVF embryos, the creation of additional human EScell lines will require the special creation of human embryos solely for research purposes, as has been demonstrated by Doug Melton at Harvard. These embryos can be created either through in vitro fertilization or by cloning. Either way, these human embryos are made and then killed for the explicit use of researchers in the laboratory.

There is this belief by some that stem cells can be harvested without damage to the embryo. Wrong. The only way to extract stem cells from a 5-7 day embryo is to remove the outer shell of the embryo and extract the inner cell mass, which consists of stem cells. This process necessarily kills the embryo, and scientists have ***never*** been able to derive an EScell without killing an embryo.

Are cures being prevented by President Bush's policy?

NO President Bush decided on August 9, 2001 to fund ESCR for the first time in history. Under President Bush's policy, 78 EScells are eligible for federal funds, and 22 EScell lines are now receiving federal dollars for research. Last year, approximately $25 million were spent on ESCR alone. There are no restrictions on private sector ESCR. Indeed, rather than using "left-over" IVF embryos, in March 2004 it was reported that ESCRer Douglas Melton created human embryos through IVF and destroyed them in order to establish 17 new EScell lines at Harvard. Harvard has proposed raising $100 million for this research, and

California and New Jersey are moving to support this research with state funds.

Furthermore, over $170 million was spent by the National Institutes of Health on human ASCR in 2002, and over $190 million in 2003. In the past few years, AScells have been used not only to treat animals, but to treat humans of a variety of diseases, such as Parkinson's, cartilage defects, blindness, systemic lupus, multiple sclerosis, rheumatoid arthritis, severe combined immunodeficiencedisease, sickle cell anemia, spinal cord injury, liver disease, and cancers such as leukemia, solid tumors, neuroblastoma, non-Hodgkin's lymphoma, and renal cell carcinoma.

Does ESCR offer therapies "right at our fingertips?"

Q A

NO Human EScells have **NOT** treated a single disease in humans. EScells have **NOT** even been used in first-stage clinical trials. In animal studies, only a few diseases have been treated with modest success. We are decades away from any approved therapies for humans using ESCR.

Don't take my word. Here's is what the industry itself is saying:

"The routine utilization of human [embryonic] stem cells for medicine is 20 to 30 years hence. The timeline to commercialization is so long that I simply would not invest. You may notice that our company has not made such investments, and we have been offered the opportunity many times." --*William Haseltine, CEO of Human Genome Sciences Inc. of Rockville, MD and a leading advocate of the research.*

Is the Bush Administration policy causing a "brain drain" of scientists?

Q A

NO Given that most other countries, including most European nations, have more restrictive ESCR policies than the US, almost no researchers have headed overseas.

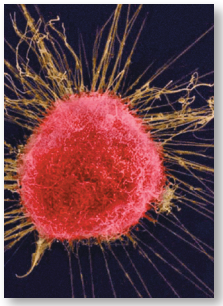
A recent article Boston Globe noted, "none of the scientists contacted by the Globe said they had seen signs of a scientific 'brain drain' that some critics predicted" (May 23, 2004).

IX. STEM CELL RESEARCH DEFINITIONS AND DISTINCTIONS

STEM CELL RESEARCH DEFINITIONS

BLASTOCYST: The human embryo between 5-7 days of development, when the stem cells develop into a cluster of cells inside an outer shell. This is the point at which researchers destroy the embryo by extracting its stem cells.

CLONING: Human cloning is a type of "asexual" reproduction, which means creating an embryo without the union of egg and sperm. This is accomplished by a technique called "somatic cell nuclear transfer," the same process used to create the cloned sheep Dolly. The nucleus from a body (somatic) cell is transferred into a female egg which has had its nuclear material removed. Then with an electric current or chemical stimulus the cloned embryo begins to divide as if it were a fertilized embryo.



DIFFERENTIATED: Acquired features of a specialized, mature cell type, i.e., skin cell, liver cell, etc.

EMBRYO: A human embryo is the earliest stage of a human organism, from the single cell up to 8 weeks of development. Embryos can be created in the lab by in vitro fertilization, with the use of sperm and egg. Embryos can also be created by cloning, which does not use sperm (see above).

IN VITRO FERTILIZATION: An assisted reproductive technique in which fertilization of egg with sperm is performed in a laboratory dish.

NON-SOMATIC CELLS: Germ cells (sex cells) such as sperm and egg cells. These are haploid (contain only 23 chromosomes).

PLASTICITY: The ability of stem cells to "differentiate" from one tissue to develop into other tissues.

PLURIPOTENT: The ability of stem cells to turn into multiple cell types. AScells were thought to have limited capability to differentiate. However, research has increasingly shown that some AScells are pluripotent.

REPRODUCTIVE CLONING: Reproductive cloning involves cloning a human embryo by "somatic cell nuclear transfer," and then implanting the embryo into a woman's uterus to produce a cloned baby. The cloning process is the same as "therapeutic cloning"; the only difference is that the purpose of creating the cloned human embryo is for baby-making rather than destructive research.

SOMATIC CELLS: Body cells. These are non-reproductive cells extracted from an individual (alive or dead) or a fetus (alive or dead). These are diploid cells (contain two sets of chromosomes totaling the 46 chromosomes which constitute the DNA of that species).

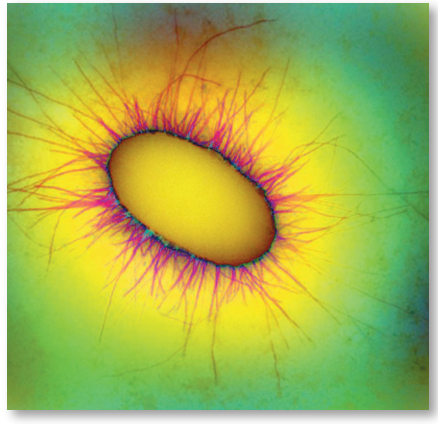
STEM CELL: These are non-specialized cells that can self-renew and "differentiate," or change, into more mature cells. In normal embryonic development, the stem cells develop into all the tissue types of an adult human. "EScells" are derived from embryos; they are not the same as embryos. "AScells" are found in adult tissues, such as bone marrow, liver, spleen, pancreas, brain, blood, fat, nose and dental pulp. Umbilical cord blood stem cells, which share characteristics of adult and EScells, are found in the placenta. The debate is not about "stem cell research" but whether we should federally fund research on EScells.

THERAPEUTIC CLONING: This involves creating a human cloned embryo by somatic cell nuclear transfer and destroying the embryo to extract stem cells. The cloning process is the same as reproductive cloning; the only difference is the purpose of creating the cloned human embryo for destructive research rather than baby-making.

UNDIFFERENTIATED: Usually an embryonic or fetal cell, which has not been programmed to a specific cell type. These can turn into almost any type of cells, and therefore are pluripotent.

STEM CELL RESEARCH DISTINCTIONS

ESCR: ESCR is perfectly legal and unrestricted. Private funds can be used to create and destroy as many embryos as researchers choose. The debate surrounds whether the federal government should fund research that destroys embryos for their stem cells. This debate involves "normal" human embryos, as opposed to cloned embryos. Federal funding of ESCR will create an incentive where taxpayer funds are directed to create and destroy human embryos. This is an unethical use of taxpayer money.



HUMAN CLONING: The creation of a human cloned embryo by a process called "somatic cell nuclear transfer (SCNT)." This is the same process that was used to create the cloned sheep, Dolly. This cloning process involves taking the nucleus of a body cell (soma), such as a skin cell, and inserting it into a female egg that had its nucleus removed. The resulting embryo will have the full set of 46 chromosomes from the donor of body cell, whereas normal embryos consist of 23 chromosomes from sperm and 23 chromosomes from egg. This process can be used to create cloned embryos for research (therapeutic cloning), or for creating a cloned baby by implanting it in a womb (reproductive cloning). The Weldon/Stupak anti-cloning bill, that passed in the 107th and 108th Congress, would ban human the cloning process (SCNT) whether the purpose is for research or reproduction. An identical bill in the Senate, the Brownback/Landrieu bill, has not passed in the Senate. Human cloning for any purpose is an unethical genetic manipulation of human life.

ASCR: This uses stem cells from the adult body and does not involve any destruction of human life. It is legal and ethical to use AScells for regenerative medicine. The NIH generously funds this non-controversial research.

X. WEBSITES OF INTEREST

www.thehumanfuture.org

www.house.gov/weldon

www.stemcellresearch.org

www.frc.org/get.cfm?i=PD02D5

www.stemcells.nih.gov